

NOT FOR PUBLICATION**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY****ORTHO-MCNEIL, et al.,****Plaintiffs,****v.****TEVA PHARMACEUTICALS USA,****Defendant.****Civil Action No.: 02-2794(GEB)****MEMORANDUM OPINION****HUGHES, U.S.M.J.**

This matter is before the Court upon the Motion of the Defendant, Teva Pharmaceuticals USA ("Defendant or Teva"), to Bifurcate Trial and to Stay Discovery pursuant to FED. R. CIV. P. 42(b). Plaintiffs, Ortho-McNeil Pharmaceutical, Inc., Johnson & Johnson, Pharmaceutical Research & Development, LLC, and Daiichi Pharmaceutical, Co., Ltd. ("Plaintiffs") oppose the Motion. The Court has reviewed the written submissions of the parties and considered the matter pursuant to FED. R. CIV. P. 78. For the reasons that follow, the Defendant's Motion is granted.

I. BACKGROUND AND PROCEDURAL HISTORY

Plaintiff, Daiichi Pharmaceutical Co., Ltd. is the owner of the '407 patent, known as Levaquin® that was licensed to Plaintiffs, Ortho-McNeil Pharmaceutical, Inc. and Johnson & Johnson Pharmaceutical Research and Development, LLC. Defendant Teva filed an abbreviated new drug application ("ANDA") with the United States Food and Drug Administration ("FDA") in order to obtain approval to manufacture and market drug products containing levofloxacin. The ANDA included a Paragraph IV Certification asserting Teva's opinion that the '407 patent

was invalid, unenforceable, or not infringed. Subsequent to Teva's filing an ANDA, Plaintiffs filed the present action as authorized by 35 U.S.C. § 271(e)(2).

In the present action, Plaintiffs allege that Teva willfully infringed its U.S. Patent No. 5,053,407 ("the '407 patent") when Teva submitted an ANDA with the United States FDA in order to obtain approval to manufacture and market a generic version of Levaquin®. Specifically, Plaintiffs allege that Defendant's infringement of its Patent '407 is willful because Defendant was "[f]ully aware that a valid and enforceable patent protect[ed] the LEVAQUIN® products. . . [when it] deliberately created copies of [them]" (Pls.['] Br. at 2).

Teva challenges the validity of the '407 patent, owned by Plaintiff, Daiichi Pharmaceutical Co., Ltd. and argues that the patent is invalid. Teva has filed counterclaims seeking a declaration that the '407 patent is invalid and an award of attorney's fees. Additionally, Defendant states that it has yet to market or sell any product containing the ingredient in issue, and thus, there are no damages, nor are any damages sought by the Plaintiffs. Therefore, Teva brings the present Motion seeking an Order from this Court bifurcating trial and staying discovery on the willful infringement issue, arguing that separating the liability issue of validity from willfulness will promote efficiency, convenience and prevent prejudice. (Def.['s] Br. at 1).

On the other hand, Plaintiffs contend that bifurcation is the exception and not the rule in patent cases and where the issues of liability and willful infringement are intertwined, as here, the moving party has the burden of showing why bifurcation is necessary. Of course, Plaintiffs argue that Defendant has failed to meet the necessary burden to bifurcate trial and stay discovery on the issue of willful infringement. Defendant challenges Plaintiffs' position that liability and willful

infringement are intertwined and argues that willful infringement is "relevant only to the issue of attorney's fees pursuant to 35 U.S.C. § 285" (*Id.* at 3). Therefore, Defendant argues that the issues of liability and willful infringement can fairly be separated for trial purposes.

In addition to the issues of liability and willful infringement being intertwined, Plaintiffs argue that bifurcating trial will impose unnecessary delay and burden upon the parties because of the costs of additional discovery, preparation, and trial. (Pls.[] Br. at 3, 6). To the contrary, Defendant argues that bifurcating trial and staying discovery on the willfulness issue will promote efficiency as well as judicial economy and offers three arguments to support its position. First, Defendant argues that should the '407 patent be found invalid, there will be no need for discovery or fact-finding on the willfulness issue because there would necessarily be no infringement, willful or otherwise. Second, Defendant contends that even if the '407 patent is found to be valid, a determination of willful infringement is relevant only to the issue of awarding attorney's fees. Lastly, Defendant asserts that attorney's fees are awarded only in exceptional cases of willful infringement and here, where there are no damages, there cannot be such a finding.

More importantly, Defendant argues that bifurcating trial and staying discovery will avoid the need for it to prematurely decide whether to waive attorney-client privilege in order to defend allegations of willfulness when the prevailing party on the invalidity issue has yet to be determined. Plaintiffs challenge Defendant's argument by reasserting that (1) bifurcation of trial will cause unnecessary delay and duplication of evidence and (2) the risk of disclosing privilege prematurely is a conflict that Defendant, itself, created when it used the same law firm for trial and opinion. Thus, Plaintiffs argue that the conflict created by Defendant itself does not justify

bifurcation. Nevertheless, Defendant requests bifurcation of trial and staying discovery on the willful infringement issue because without it, it would otherwise cause a significant risk of unfair prejudice. (*See* Def.[']s Mem. at 11).

II. DISCUSSION

Pursuant to FED. R. CIV. P. 42(b), a court may bifurcate a trial if it would be "in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy[.]" FED. R. CIV. P. 42(b). "[T]he decision to bifurcate . . . is a matter to be decided on a case-by-case basis and must be subject to an informed discretion by the trial judge in each instance." *Lis v. Robert Packer Hospital*, 579 F.2d 819, 824 (3d Cir. 1978), *cert. denied*, 429 U.S. 955 (1978). The moving party has the burden of demonstrating that judicial economy would best be served by bifurcating the case, and that no party would be unduly prejudiced by having separate trials. *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 180 F.R.D. 254, 256 (D.N.J. 1997); *Spectra-Physics Lasers, Inc. v. Uniphase Corp.*, 144 F.R.D. 99, 101 (N.D.Cal. 1992).

Bifurcation would be unwarranted if it would result in duplication of effort, inconvenience to the parties and the Court, undue delay, unreasonable expense, or prejudice. *Princeton Biochemicals, Inc.*, 180 F.R.D. at 256; *Johns Hopkins University v. Cellpro*, 160 F.R.D. 30, 32 (D.Del. 1995).

A. Bifurcating Liability

Federal courts have bifurcated patent cases when the party seeking bifurcation has demonstrated that the issues are complex and would involve the presentation of extensive evidence, which could result in jury confusion and prejudice to the parties. *Princeton*

Biochemicals, Inc., 180 F.R.D. at 257; *Spectra-Physics Lasers, Inc.*, 144 F.R.D. at 101; *B. Braun Medical Inc. v. Abbott Laboratories*, 1994 WL 468155, at *1 (E.D.Pa. August 24, 1994).

In *Smith v. Alyeska*, the court noted:

In the normal case separate trial of issues is seldom required, but in a patent infringement suit considerations exist which suggest that efficient judicial administration would be served by separate trials on the issues of liability and damages. The trial of the damages question in such a suit is often difficult and expensive, while being easily severed from the trial of the questions of validity and infringement of the patent. A preliminary finding on the question of liability may well make unnecessary the damages inquiry, and thus result in substantive saving of time of the Court and counsel and reduction of expense to the parties. Moreover, separate trial of the issue of liability may present counsel the opportunity to obtain final settlement of that issue or appeal without having reached the often time-consuming and difficult damages question.

Smith v. Alyeska, 538 F.Supp. 977, 982-83 (D.Del. 1982), *aff'd*, 758 F.2d 664 (Fed. Cir. 1984), *cert. denied*, 471 U.S. 1066 (1985) (quoting *Swofford v. B & W, Inc.*, 34 F.R.D. 15, 19-20 (S.D. Tex. 1963) *aff'd*, 336 F.2d 406 (5th Cir. 1964), *cert. denied*, 379 U.S. 962 (1965)).

In the present case, the Court finds that the issues are not necessarily complex, as it involves only one patent, specifically, the '407 patent. Additionally, there are no issues of damages to be resolved because there has been no marketing or sale of the product. Nevertheless, courts have considered and balanced other factors such as the prejudice that may be caused for a party should bifurcation not be ordered. *See* FED. R. CIV. P. 42(b). Here, the Court finds that while the validity of the patent at issue is not complex, the issue of "liability and willfulness are two distinct causes of action" as the court found in *Princeton Biochemicals, Inc.*, and thus have different elements which must be proved. *Princeton Biochemicals, Inc.*, 180 F.R.D. at 258 fn.3. Moreover, the Court finds that at this juncture, the potential prejudice to the

Defendant outweighs the potential waste of resources as the Plaintiffs suggest. Accordingly, the Court is unconvinced that there would be any substantial overlap or duplicity as a result of bifurcating trial and discovery with regards to liability and willfulness. Lastly, the Court agrees with the Defendant that once the validity of the patent is determined and infringement is or is not found, then the Court can speedily proceed with its determination of willfulness. Furthermore, the Court finds that bifurcation, while certainly not the rule but the exception, would nevertheless, promote efficiency and judicial economy in this particular case.

B. Willful Infringement and Exceptional Case Issue

Defendant moves to bifurcate and stay discovery on the willful infringement/exceptional case issue arguing that a determination of the validity of the '407 patent will provide more focus as to discovery on the willful infringement/exceptional case issue. Defendant contends that there is no need to expend additional resources and burden parties regarding damages when Plaintiffs did not even seek damages in the present case. The Court agrees with the Defendant that conducting discovery on issues surrounding willful infringement is premature at this point, especially, when no damages have been sought by the Plaintiffs. Accordingly, there is no need at this time to determine willful infringement and even more so, the exceptional case issue which is related to a finding of willful infringement.¹ Therefore, the Court finds that a two-step process of

¹Both Plaintiffs and Defendant have requested an award of attorneys' fees should either prevail in the lawsuit. An award of attorneys' fees in patent cases is granted only in exceptional cases where the infringement was found to be willful. However, a finding of willful infringement does not automatically mandate a court to award attorneys' fees. *Whelan v. A. Ward Enterprises, Inc.*, 2002 WL 1745614, at * 5 (E.D.Pa. July 23, 2002) (citing *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992)). There are nine factors that the *Read* Court listed in determining whether to award an attorney's fees in patent infringement cases. *Read*, 970 F.2d at 827. At this time, the Court finds it unnecessary to even review those nine factors.

determining first the liability and then damages, if any, will not deter efficiency and judicial economy.

More importantly, the Court is persuaded by Defendant's argument that the issue of willful infringement should be bifurcated because discovery on that issue would involve the disclosure of attorney-client communications. In *Quantum v. Tandon*, 940 F.2d 642, 643-44 (Fed. Cir. 1991) the Court stated:

Proper resolution of the dilemma of an accused infringer who must choose between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found, is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege. An accused infringer, therefore, should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willingness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found. Trial courts thus should give serious consideration to a separate trial on willfulness whenever the particular attorney-client communications, once inspected by the court, *in camera*, reveal that defendant is indeed confronted with this dilemma.

Id. at 644; see also *Princeton Biochemicals, Inc.*, 180 F.R.D. at 259. As federal courts in this District have properly held, "willful infringement is more appropriately determined after liability has been established, thereby avoiding even the possibility of prejudice to a patent defendant's litigation rights." *Princeton Biochemicals, Inc.*, 180 F.R.D. at 258.

Moreover, the Court is unconvinced at this juncture that the proofs required to demonstrate Defendant's willfulness, when it infringed against Plaintiffs' patent '407, are intertwined with the proofs regarding the validity of the patent. Accordingly, the Court cannot foresee that there will be any significant overlapping of evidence. In addition, as the parties have

pointed out the fact that there is only one patent at issue in the present litigation should minimize any substantial duplication of evidence which might have increase costs. More importantly, the Court is mindful of the fact that allowing Plaintiffs to pursue discovery on the willful infringement issue may cause Defendant to prematurely waive its attorney-client privilege thereby possibly prejudicing its case. Therefore, the Court finds that bifurcating trial and staying discovery as to the issue of willful infringement/exceptional case is appropriate in this particular case.

III. CONCLUSION

For the reasons stated above, Defendant Teva Pharmaceuticals' Motion to Bifurcate Trial and Stay Discovery on the Willful Infringement/Exceptional Case Issue is granted. Discovery on willfulness is stayed and shall commence after the parties conduct a meeting and confer pursuant to FED. R. CIV. P. 26(f) to determine the timing and parameters of such discovery. In addition, trial on liability and willfulness will be bifurcated.

An appropriate Order accompanies this Memorandum Opinion.

Dated:

 28, 2003